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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,678	01/23/2001	Axel Ullrich	038602-1082	4384

7590 03/26/2002

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EXAMINER

SPECTOR, LORRAINE

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 03/26/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.



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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on _____

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire one month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 1-46 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) _____ is/are rejected.

Claim(s) _____ is/are objected to.

Claims 1-46 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Part III: Detailed Office Action

Notice: Effective June 18, 2000, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit **1647**.

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Restriction Requirement:

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, 11 and 18-21, drawn to nucleic acids encoding Flk-1 receptor protein, fusion proteins comprising such, methods of making, cells, and assays, classified in class 435, subclass 69.7.
- II. Claim 10, drawn to Flk-1 receptor protein, classified in class 530, subclass 350.
- III. Claims 12 and 13, drawn to antisense oligonucleotides, classified in class 536, subclass 24.1.
- IV. Claims 14-17, drawn to anti-Flk-1 antibodies, classified in class 530, subclass 387.9.
- V. Claims 22-24, drawn to protein binding assays for detecting VEGF agonists/antagonists, classified in class 435, subclass 7.1.
- VI. Claims 25-27, 31 and 33, drawn to *in vivo* methods of modulating Flk-1 tyrosine kinase activity using an agonist, classified in class 424, subclass dependent upon species.
- VII. Claims 25, 28-30, 32, 34 and 35 drawn to *in vivo* methods of modulating Flk-1 tyrosine kinase activity using an antagonist, classified in class 424, subclass dependent upon species.
- VIII. Claim 36-43, drawn to truncated Flk-1 proteins and recombinant methods of making such, and methods of treatment using such classified in class 514, subclass 2.
- IX. Claim 44, drawn to methods of identifying phosphorylation inhibitors, classified in

class 435, subclass 7.2.

X. Claims 45 and 46, drawn to compounds that inhibit phosphorylation of Flk-1, classification dependent upon species.

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The inventions are distinct, each from the other because:

The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in claim 8. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

Some of the antisense oligonucleotides of Invention I are related to the nucleic acids of Invention III by virtue of being subsequences of longer disclosed sequences. However, these inventions are patentably distinct both because the nucleic acids of Invention III are not required for Invention I, and because they are used in materially different processes which processes are completely different and distinct. The arts of antisense therapy and recombinant production of proteins are separate and distinct, and require non-coextensive searches.

Inventions I and IV are drawn to physically, functionally and patentably distinct products wherein each product does not require the others, the products have different uses and means of manufacture, and the products require non-coextensive searches. Accordingly, restriction is proper.

Inventions I and each of Inventions V and VI are separate and distinct, wherein the products of Invention I are not required for Invention V or VI, and wherein the methods of Invention I, V and VI involve different starting and ending materials, different method steps, and achieve distinct goals.

Accordingly, restriction is proper.

Inventions I and VII are separate and distinct wherein the two sets of methods involve different starting and ending materials, different method steps, and achieve distinct goals, and wherein the products of Invention I cannot be used in the methods of Invention VII. Accordingly, restriction
5 is proper.

Inventions I and VIII are separate and distinct wherein the DNA of Invention VIII encodes a truncated protein and therefore requires analysis of alteration of genetic elements comprising protein encoding regions. Such consideration is not required for analysis of either the DNA molecules or methods of Invention I. Further, the products of Invention VIII are neither made by nor
10 used in the methods of Invention I. Accordingly, restriction is proper.

Inventions I and IX are separate and distinct wherein the two sets of methods involve different starting and ending materials, different method steps, and achieve distinct goals, and wherein the products of Invention I are not required for the methods of Invention IX. Accordingly, restriction is proper.

15 Invention X is separate and distinct from each of Inventions I-IV, VI, and VIII wherein the products of Invention X are physically and functionally distinct from the other products, and wherein the products of Invention X can neither be made by nor used in the methods of the other inventions.

Inventions II-IV are drawn to physically, functionally and patentably distinct products wherein each product does not require the others, the products have different uses and means of manufacture,
20 and the products require non-coextensive searches. Accordingly, restriction is proper.

Inventions II and each of Inventions V, VI and IX are related as product and process of use.
The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product
25 (MPEP § 806.05(h)). In the instant case the product may be used in any of the three distinct methods, or alternatively in a method of making the antibodies of Invention IV.

The products of Inventions II, VII and VIII are physically, functionally and patentably distinct

products wherein each product does not require the others, the products have different uses and means of manufacture, and the products require non-coextensive searches. Accordingly, restriction is proper.

5 The products of Invention III are separate and distinct from each of the methods of Inventions V-VII and IX, wherein the products are neither made by nor used in the methods. Accordingly, restriction is proper.

10 The products of each of Inventions III and IV are related to Invention VIII as physically, functionally and patentably distinct products wherein each product does not require the others, the products have different uses and means of manufacture, and the products require non-coextensive searches. Accordingly, restriction is proper.

The antibodies of Invention IV are separate and distinct from the methods of Inventions V and IX, wherein the antibodies are not made by nor required for the methods. Accordingly, restriction is proper.

15 *Some* of the antibodies of Invention IV are related to Invention VI, and some to Invention VII, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product may be used for the purification of Flk-1 protein.

20 The products of Invention IV are separate and distinct from each of the methods of Inventions V and IX, wherein the products are neither made by nor used in the methods. Accordingly, restriction is proper.

25 Inventions V, VI, VII, and IX are drawn to separate and distinct methods wherein the methods involve different starting and ending materials, different method steps, and achieve distinct goals. Accordingly, restriction is proper.

The methods of Invention V are separate and distinct from the products and methods of Invention VIII wherein the products cannot be made by nor used in the methods of Invention V, and

wherein the two sets of methods involve different starting and ending materials, different method steps, and achieve distinct goals. Accordingly, restriction is proper.

The methods of Invention V are separate and distinct from the products of Invention X wherein the products cannot be made by nor used in the methods.

5 The methods of Invention VI are separate and distinct from the products of Invention VIII wherein the products cannot be made by nor used in the methods.

Inventions VII and X are drawn to separate and distinct methods wherein the methods involve different starting and ending materials, different method steps, and achieve distinct goals. Accordingly, restriction is proper.

10 The products of Invention VIII are separate and distinct from the methods of Invention IX, wherein the products are not made by the methods, and wherein the products are capable of separate use, i.e. in a method of inhibiting angiogenesis. Accordingly, restriction is proper.

15 Finally, while the products of Invention X may be *identified* by the methods of Invention IX, assay is not manufacture, and the products are not made by the methods. Further, the products are capable of separate use, such as in a method of inhibiting angiogenesis.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Advisory Information:

25 Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached at (703)308-4623.

30 Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

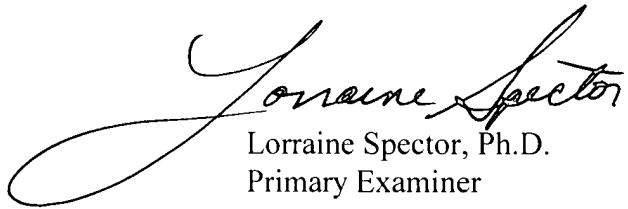
Certain papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should

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be faxed to Examiner Spector via telephone number 703-746-5228. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of 5 duplicate papers in the Office.

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Lorraine Spector
Lorraine Spector, Ph.D.
Primary Examiner

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3/22/02